

REMARKS

This amendment responds to the Office Action dated September 18, 2006. The general thrust of the Office Action is that the examiner does not think that the patent specification discusses “no longitudinal attachment” of the retaining clips on the proximal handle. See Office Action, pages 4 - 5, para. 10 - 13. The specification clearly discloses that the retaining clips “laterally” attach or clip-on the guide wire. Further, the examiner, in ¶ 19 of the Office Action, states “[r]egarding the lateral attachment of an actuation sleeve...” Therefore, the examiner believes that the claims specify lateral attachment to the guide wire (actuation sleeve, or first and second movable member).

In ¶ 7 of the Office Action, the examiner stated that the specification does not disclose the claim limitation in claims 10, 17 and 18 “transversely attachable and not longitudinally attachable.” See also claim rejection in Office Action ¶ 13. The Applicant respectfully disagrees. The specification states:

The proximal actuator, when transversely or laterally (not longitudinally) removably mounted, permits the operator to move one wire or tube with respect to the other wire or tube.

¶ 002.

The proximal actuator of the present invention, when transversely or laterally (not longitudinally) removably mounted on the distal end of the control system, permits the operator to move one wire or tube with respect to the other wire or tube thereby affecting the operation of the medical device at the distal end of the control system.

¶ 135.

An important feature of the present invention is that the proximal actuator need not be axially threaded onto or off of the guide wire-actuator sleeve system. The proximal actuator is removably mounted to the tube in a tube or wire over a wire system by transversely or laterally attaching the proximal actuator at a desired location on the guide wire-actuator sleeve.

¶ 149

These statements provide support for the claim language in claims 10, 17 and 18

“transversely attachable and not longitudinally attachable.” It is respectfully requested that the examiner withdraw this rejection.

The examiner’s statement that the specification does not show “any structure on the proximal actuator that would prohibit longitudinal attachment” is not accurate. The specification, as noted above, on several occasions does state that lateral, not longitudinal, attachment is an important feature of the present invention. “The proximal actuator need not be axially threaded onto or off of the guide wire-actuator sleeve system,” ¶ 149, and this “no axial threading” feature is very important when handling catheter guide wires. It is well known that access to the exposed longitudinal end of the guide wire is sometimes compromised by other medical devices. Hence, the “transversely attachable and not longitudinally attachable” in claims 10, 17 and 18 is important and is shown in that FIGs. 36, 37, 38 show lateral attachment only, not longitudinal or axially threaded attachment. “The proximal actuator is removably mounted to the tube in a tube or wire over a wire system by transversely or laterally attaching the proximal actuator at a desired location on the guide wire-actuator sleeve.” ¶ 149. Axially attachable systems cannot operate to attach “at a desired location.” Axially attachment is only at one location, at an axial end, not at “at a desired location” which is reflected in the claims as “transversely attachable and not longitudinally attachable” in claims 10, 17 and 18.

The changes to ¶ 142 of the specification relative to laterally opening and laterally closing clips do not introduce new matter because, at numerous locations, the specification discusses lateral attachment (see ¶ 149) and the description of the operation of the “retaining devices” in ¶ 142 - 149 and FIGs. 36 - 39 leave no doubt that lateral or transverse attachment is used, not axial nor longitudinal attachment.

In ¶ 8 of the Office Action, the examiner objects to claims 7 and 45 relative to whether

the first retaining device moves. Claims 1, 16, 18, and 39 are amended to clarify that the actuator body has “a first retaining device and a movably mounted second retaining device” thereon. See claim 1. This clarifies that the first retaining device is on the actuator body or handle (claim 18, 39) and the second retaining device is movably mounted with respect thereto, and, more importantly, movable with respect to the first retaining device. Please withdraw this objection since the independent claims now conform to claims 7 and 45.

The examiner rejected claims 1 - 16, 17, 18 - 31 and 39 - 52 in light of the item discussed above with respect to independent claims 1, 16, 18, and 39, now amended to clarify that the actuator body has “a first retaining device and a movably mounted second retaining device” thereon. Please withdraw this rejection since the independent claims are now clarified on this point.

Claim 17 has been changed per the examiner’s request. (see ¶ 9 of the Office Action).

Claim 1 has been amended to consistently refer to “actuation sleeve” since the earlier claim referred to “actuator sleeve” and “actuation sleeve.” This was a typographic error.

With respect to the prior art rejections, independent claims 1, 16, 18, and 39 are amended to refer to the retaining devices having a laterally openable clip and having a corresponding laterally openable clip, which laterally removably attach to the guide wire components (actuation sleeve, or first and second movable member). The prior art does not show this feature.

Also, all the claims now refer to medical devices in the body of the claim and, as such, the references which do not operate on medical devices are not relevant prior art.

In the Office Action on pages 5 - 9, para. 14 - 27, the patent examiner rejects claims 1, 7- 9, 11-16, 32 - 39 and 46 - 52 as being non-patentable in view of certain prior or pre-existing

technology or art disclosed in the following references: U.S. Patent No. 4,576,529 to Forrer (Forrer '529) and U.S. Patent No. 6,193,125 to Grover (Grover '125).

U.S. Patent Nos. 4,576,529 to Forrer and 6,193,125 to Grover relate to hand tool clamp systems and not to "a medical device" as is claimed in the present invention. Forrer '529 is a clamping system for a hand drill (see Abstract, last 4 lines) and Grover '125 is a tool holder for a hand drill. Col. 5, line 23 (herein "5/23"). Forrer '529 and Grover '125 are not relevant art because the medical device operated by the claimed actuator moves the guide wire small distances with respect to the actuation sleeve. The clamp systems and holders of Forrer '529 and Grover '125 permit adjustment of hand drills and tools and do not, in any manner, relate to the medical use of a guidewire, an actuation sleeve nor a distally located medical device at the end of the guidewire - actuation sleeve combination.

The Examiner, in the Office Action, indicated that items in the preamble, such as the actuation sleeve (and now the inner tube or wire which runs in the actuation sleeve) is not properly part of the patentability analysis for the claims. Claims 1 and 16 now state the medical device is "coupled to said actuation sleeve." Claims 18, 32 and 39 refer to a frame as part of the medical device. It is respectfully submitted that the MPEP states that structure in the preamble is part of the claim if the item is tied to other structure recited in the body of the claim.

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at

issue was directed to a driver for setting a joint of a threaded collar*>< however>,< the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

MPEP § 2111.02(I)

Lastly, the examiner did not reject claims 2 - 6, 10, 17 - 31 and 40 - 45 based upon prior art. Therefore, with the changes set forth herein, those claims should be considered patentable over the references.

Therefore, Applicant respectfully requests that the Examiner withdraw the rejections against claims 1 - 52 and allow the claims.

Respectfully submitted,

By _____/Robert Kain/_____
Robert C. Kain, Jr.
Reg. No. 30,648

Fleit, Kain, Gibbons, Gutman, Bongini & Bianco, P.L.
750 Southeast Third Avenue, Suite 100
Ft. Lauderdale, FL 33316-1153
Telephone: 954-768-9002
Facsimile: 954-768-0158

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_____/Robert Kain_____
Robert C. Kain, Jr.
Reg. No. 30,648 \WTiger\data

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